PROFILE OF ONGOING SURVEILLANCE

During the development of the research agenda, the SAG initiated its Ongoing Surveillance program to review emerging scientific information on the potential health effects of wireless technology. Through daily monitoring of all new information in the field, the SAG's intent was to be ready to recommend immediate solutions — through the Risk Management program — for any problems that might arise.

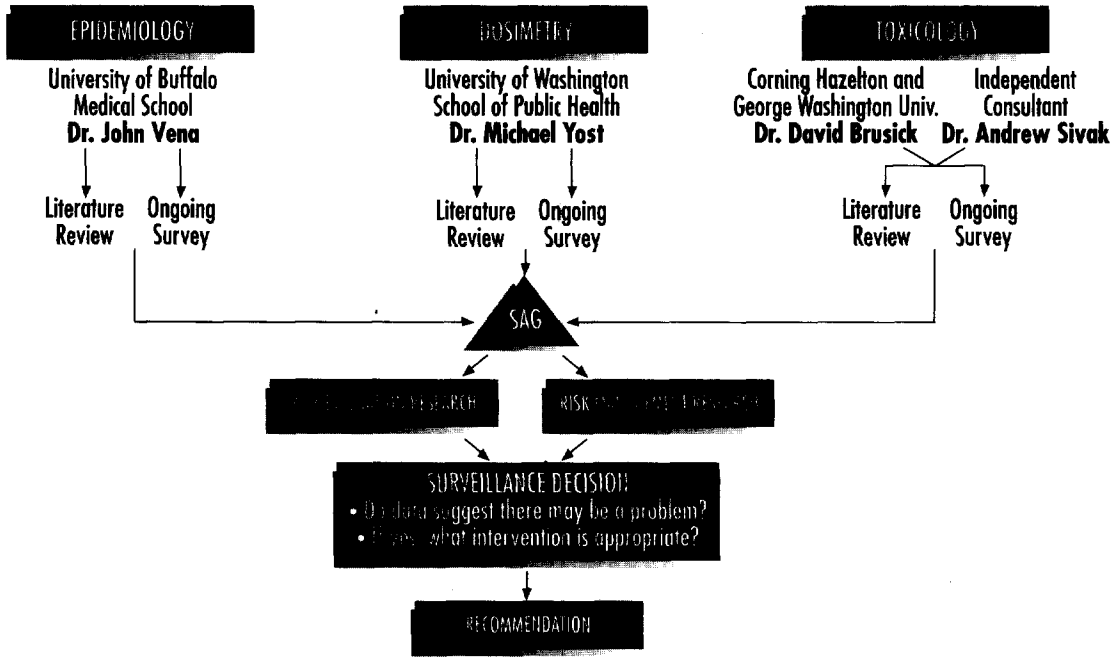
As a first step, to ascertain the current state of knowledge about the potential health effects of cellular telephones and other wireless technologies and to identify data gaps and needs for additional research, the SAG directed a critical review and evaluation of all available dosimetry, toxicology, epidemiology, clinical, and other data that might arguably be relevant to exposures to radiofrequency radiation. This effort was conducted in accordance with widely accepted quality and interpretational criteria, and it covered authoritative scientific reviews; published scientific databases, standards, and guidelines; peer-reviewed scientific literature; available unpublished data; and information derived from personal interactions with scientists involved in relevant work.

In August 1994, the SAG published *Potential Public Health Risks from Wireless Technology: Research Agenda for the Development of Data for Science-Based Decision-making*, a document which helped more clearly define the parameters of the Ongoing Surveillance program.

The SAG also established a scientific literature monitoring program to conduct daily reviews of new scientific literature in each of the three broad areas central to the SAG's work. Dr. John Vena, of the State University of New York at Buffalo, School of Medicine, was selected for the ongoing literature review of epidemiology topics. Dr. Michael Yost, of the University of Washington, School of Public Health, was selected to monitor and review the literature on dosimetry. Dr. David Brusick, of Corning Hazelton, Inc., and Dr. Andrew Sivak, an independent consultant, were selected to review literature concerning toxicology-related science.

During Phase One, the SAG built a rapid trigger for public health interventions into the program. If investigators identify any danger or potential hazard at any time during their evaluations, the program will move immediately into a risk-management mode.

ONGOING SURVEILLANCE OF SAG SCIENTIFIC PROGRAM: Data Monitoring and Decisionmaking Process

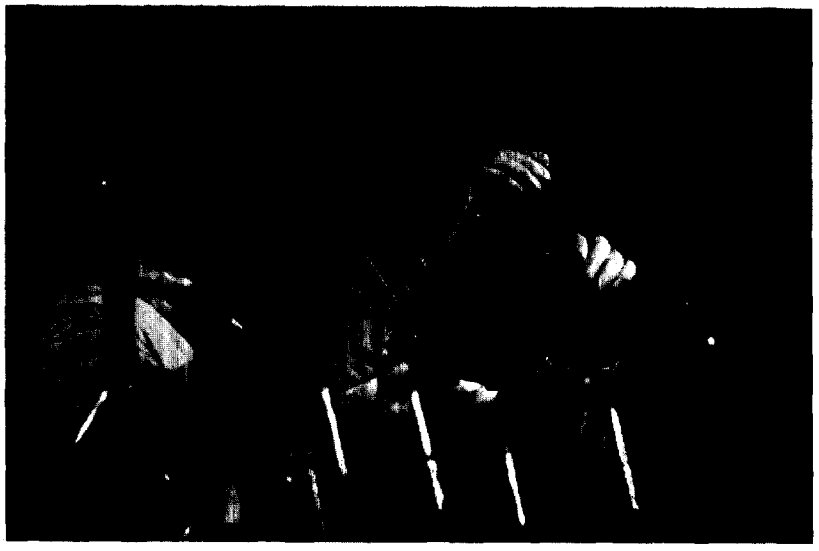


At the beginning of the Ongoing Surveillance program, the SAG developed and distributed a survey regarding international scientific research pertaining to wireless technology. Responses identifying incomplete or unpublished research and investigators working on potentially relevant projects were input as the start of the SAG's international research database.

During Phase One, the SAG coordinated the formation of numerous independent expert panels to assist in the evaluation of emerging scientific information. These panels included

- Dosimetry/Exposure System Expert Panel
- Single Cell Gel Assay Expert Panel
- Tumor Promotion Expert Panel
- Tissue Type Expert Panel
- Epidemiology Exposure Metric Expert Panel

The SAG actively participated in numerous international scientific organizations and activities, including the Commsphere International Symposium, the Bioelectromagnetics Society Meeting (Copenhagen), and the European Cooperative Organization on Science and Technology's



Ongoing Surveillance enables the SAG to identify and respond to potentially important research developments

Action 244 (COST 244). The objective of COST 244's Telecommunications Research Effort is to obtain general insight into state-of-the-art research on Biomedical Effects of Electro-magnetic Fields. The WTR's future participation in this international effort will encourage multidisciplinary collaboration between experts in different fields, such as medicine, biology, and electrical engineering.

The SAG's surveillance program enabled the SAG in several instances to identify promptly, and respond quickly, to potentially important developments. For example, the program produced early notice of research suggesting that radiofrequency radiation may cause damage to DNA under certain conditions. Similarly, the SAG's surveillance program detected the potential of wireless instruments to cause problems for users of pacemakers.

In both instances, the SAG informed the Food and Drug Administration (FDA) of these developments, offering research information to assist the FDA in making prompt determinations about whether immediate risk-management responses were necessary.

PROFILE OF RISK EVALUATION RESEARCH

FOUNDING PRECEPTS

The risk evaluation research component of the SAG's program was established to identify and address the data gaps and research needs that currently preclude definitive statements about whether wireless communication instruments can pose health risks.

The SAG began by forming three standing committees: the Toxicology Committee chaired by Dr. Ian C. Munro, the Dosimetry Committee chaired by Dr. Arthur W. Guy, and the Epidemiology Committee chaired by Dr. George L. Carlo. Each committee chair was responsible for gathering input from a variety of sources within his area of responsibility. During Phase One, the SAG elicited the views of top scientists in the world from academia, government, industry, and private laboratories. To do this, the SAG solicited written suggestions and proposals, and held numerous open meetings, workshops, and symposia. Members of the SAG also visited laboratories equipped to conduct research on radiofrequency radiation and queried experienced personnel from these laboratories about the advantages and disadvantages of various potential research approaches.

In its *Research Agenda* document, the SAG included an extensive review of the current state of knowledge pertinent to the health effects of wireless technology. The document analyzed the strengths and weaknesses of existing studies and identified key data gaps and research needs. The document also discussed the hypotheses to be tested; the protocols, guidelines, and assumptions to be used; the quality-assurance standards to be applied; and the plan for conducting extramural research in Phase Two.

As described in the *Research Agenda*, the SAG/WTR's research program will operate under the following guiding principles.

Under **Guiding Principle Number One**, the research program will encompass a three-tiered approach to both developing information and placing appropriate weight on specific scientific findings.

Tier I studies will develop radiofrequency radiation exposure systems relevant to wireless communication instruments including cellular telephones and will test hypotheses in experimental biological systems in accordance with standard approaches to product safety evaluation. The research methods employed will include those widely accepted as being indicative of carcinogenic potential, as well as other adverse outcomes.

PRINCIPLES GUIDING THE RESEARCH PROGRAM

- **Guiding Principle Number One**
  - The program will take a three-tiered approach to research:
    - Tier I studies will test hypotheses in experimental systems in accordance with accepted principles of consumer product safety evaluation
    - Tier II will encompass epidemiology and longitudinal surveillance of wireless communication instrument users
    - Tier III studies will be conducted to address mechanistic and methodology issues
- **Guiding Principle Number Two**
  - The research program will be limited to studies directly relevant to the potential public health impact of wireless communication technology
- **Guiding Principle Number Three**
  - The research program will include only studies conducted in accordance with Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs) and Good Epidemiology Practices (GEPs)
- **Guiding Principle Number Four**
  - All studies conducted under the research program will be subjected to ongoing, scientific peer review and will be submitted to the peer-reviewed scientific literature for publication

KEY QUESTIONS IN TOXICOLOGY (TIER I)

- What factors need to be considered when extrapolating experimental results to users of wireless communication instruments?
- Are exposures at 850 or 950 MHz comparable to exposures at 2450 MHz?
- How can principles of chemical carcinogenesis testing be adapted to radiofrequency radiation exposures?
  - Role of genotoxicity assays (*in vitro* and short-term *in vivo*)
  - Role of research on tumor promotion/progression
  - Need for conduct of a long-term animal bioassay
  - Development of appropriate *in vitro* and *in vivo* exposure systems

KEY QUESTIONS IN EPIDEMIOLOGY (TIER II)

- Are phone records usable, can they be obtained and downloaded into record databases?
- Is there a correlation between phone records and self-reported phone use?
- What is the mortality rate by cause-of-death for portable cellular phone users versus mobile phone users?
- Do phone records accurately identify the primary user of the phone?
- What are the issues involved in exposure assessment?
  - Dosimetry of exposure-SAR (exposure variable determination)
  - Do 10 one-minute phone calls equal one 10-minute phone call?
  - Potential confounding factors such as jewelry, wire-rimmed glasses
  - Position of phone, antenna up or down
  - Occupational exposure
  - Cell density, proximity to a base station and power determinations
  - Outcome measures—brain cancer, parotid gland tumors, acoustic neuromas, and leukemia

"A major objective of the SAG is to ensure that all research supported in its program is based on the best and most accurate dosimetry that science can provide."

Dr. Arthur W. Guy
January 1995

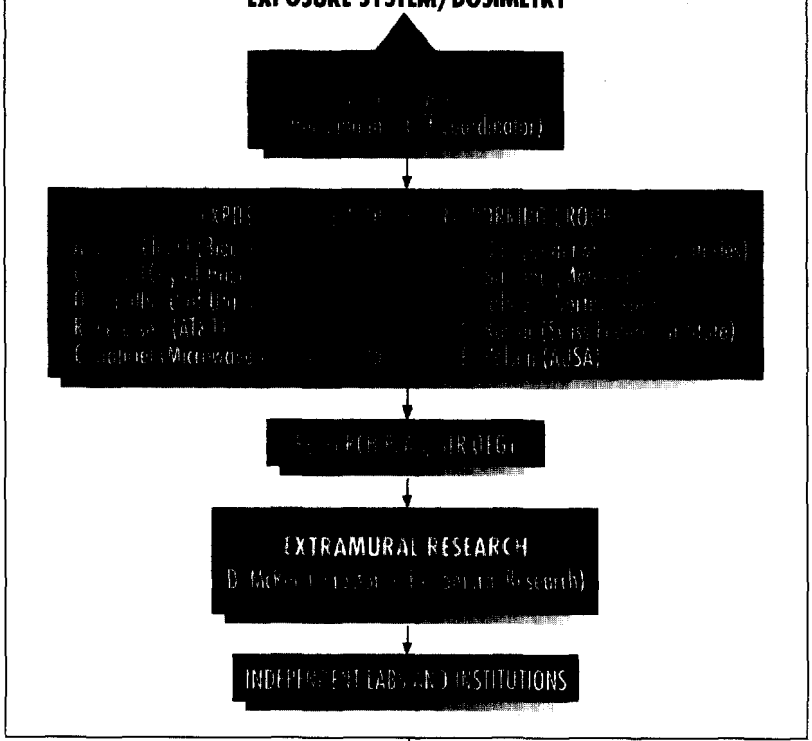
Tier II studies will encompass epidemiological evaluations and longitudinal surveillance of cellular telephone users, employing appropriate measures of real-life exposures.

Tier III studies will be conducted as needed to address mechanistic and methodological issues arising from studies conducted under Tiers I and II which are suggestive of a public health risk.

Under **Guiding Principle Number Two**, the research program will be limited to studies directly relevant to the potential public health impact of wireless communication technology. More specifically, *in vivo* studies will address near-field exposures to radiofrequency waves consistent with the powers, frequencies, and modulations associated with wireless communication instruments, including cellular telephones.

Under **Guiding Principle Number Three**, the research program will include only studies conducted in accordance with GLPs (Good Laboratory Practices), GCPs (Good Clinical Practices), and GEPs (Good Epidemiology Practices). These minimum standards are required by regulatory agencies charged with ensuring that dangerous products do not enter into commerce.

RISK EVALUATION RESEARCH: Structure of Exposure System Dosimetry Research Component and Decisionmaking Process



Under **Guiding Principle Number Four**, procedures will be instituted to assure the highest quality experimental data and scientific interpretation. All studies conducted pursuant to the *Research Agenda* will be subjected to rigorous, ongoing, scientific peer review, both by the WTR and through the Peer Review Board coordinated by the Harvard University Center for Risk Analysis. In addition, investigators funded through the program will be required to submit their work for publication in the peer-reviewed scientific literature.

▲ DEFINITION OF DOSIMETRY

Dosimetry is the science concerned with quantification of exposure — the "dose" — of an agent that impinges on biological tissue. In the field of non-ionizing radiation dosimetry, the term refers to the measurement or calculation of energy deposition in living tissue. Absorbed energy is directly related to the electromagnetic fields in the object or tissue, but these internal fields are usually significantly different from those impinging on the object or tissue. The object's size and shape, electrical properties, orientation with respect to the incident fields, and the frequency of the incident fields may all affect the internal fields and, therefore, the

level and distribution of energy absorption. For non-ionizing radiation such as emissions from wireless communication instruments, dosimetry is crucial for interrelating thresholds of biological effects in exposed living systems and cells, and between different species.

In the context of the wireless technology research program, dosimetry activities include:

- Quantification of exposure from wireless communication instruments in humans or human models
- Determination of the most appropriate dosimetric methods for such quantification
- Development of exposure systems for experimental animals capable of accurately reproducing exposures sustained by humans using wireless communication instruments

HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN DOSIMETRY RESEARCH

Research Agenda Literature Review

General information on dosimetry and methods of dosimetric quantification was compiled for the SAG's *Research Agenda*. The *Agenda* also included a review of the published dosimetric literature on wireless communication instruments.

Bioelectromagnetics Society (BEMS) Annual Meeting

SAG members participated in the 1994 BEMS conference in Copenhagen, Denmark, and presented information on the research program. To gather information and encourage coordinated efforts in the United States and abroad, the SAG hosted an event in conjunction with the meeting for investigators conducting research on wireless technology. The WTR hosted a workshop at the start of the 1995 BEMS Annual Meeting.

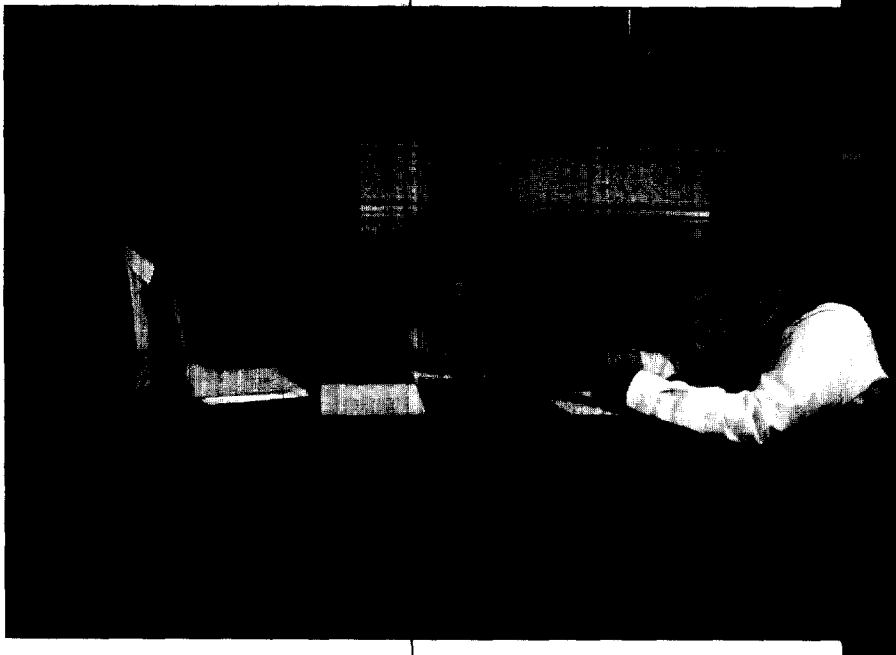
COST 244 Working Group

The European COST Action 244 held one of its first meetings in November 1994 in Rome, Italy. Part of the meeting involved a validation effort for the Finite Difference Time Domain (FD-TD) method — a computerized mathematical method of exposure calculation — for application to wireless communication instruments. The SAG funded two investigators, Dr. Om Gandhi of the University of Utah and Mr. Kwok Chan of City of Hope National Medical Center (Duarte, California), to participate in the validation effort.

"MC members have decided that cooperation with the Scientific Advisory Group (SAG) is welcomed. This institution will be continuously informed about COST 244 activities and instructions for official participation on an institutional basis will be sent to the SAG."

Instructions from Technical Secretariat COST 244 Action Group European Commission

November 1994



"One of the objectives of the SAG is to sponsor good science that is related to the potential impact of the use of wireless communication instruments on human health. To meet this objective, our toxicology staff has been evaluating work already done and proposals already submitted. We are now assigning research priorities using the best science available."

Dr. Ian C. Munro

December 1994

Development of Overall Dosimetry Work Plan

The efforts of the SAG Dosimetry Committee and expert panels during Phase One resulted in the development of the overall dosimetry strategy and work plan. The plan involves the collaborative effort among scientists from universities and private laboratories to:

- Validate the FD-TD method for application to wireless communication instruments
- Establish reliable data on human exposure
- Use human exposure data to develop and test exposure systems for cell cultures and experimental animals
- Implement the resultant exposure systems in large-scale studies
- Develop a certification program for wireless instruments

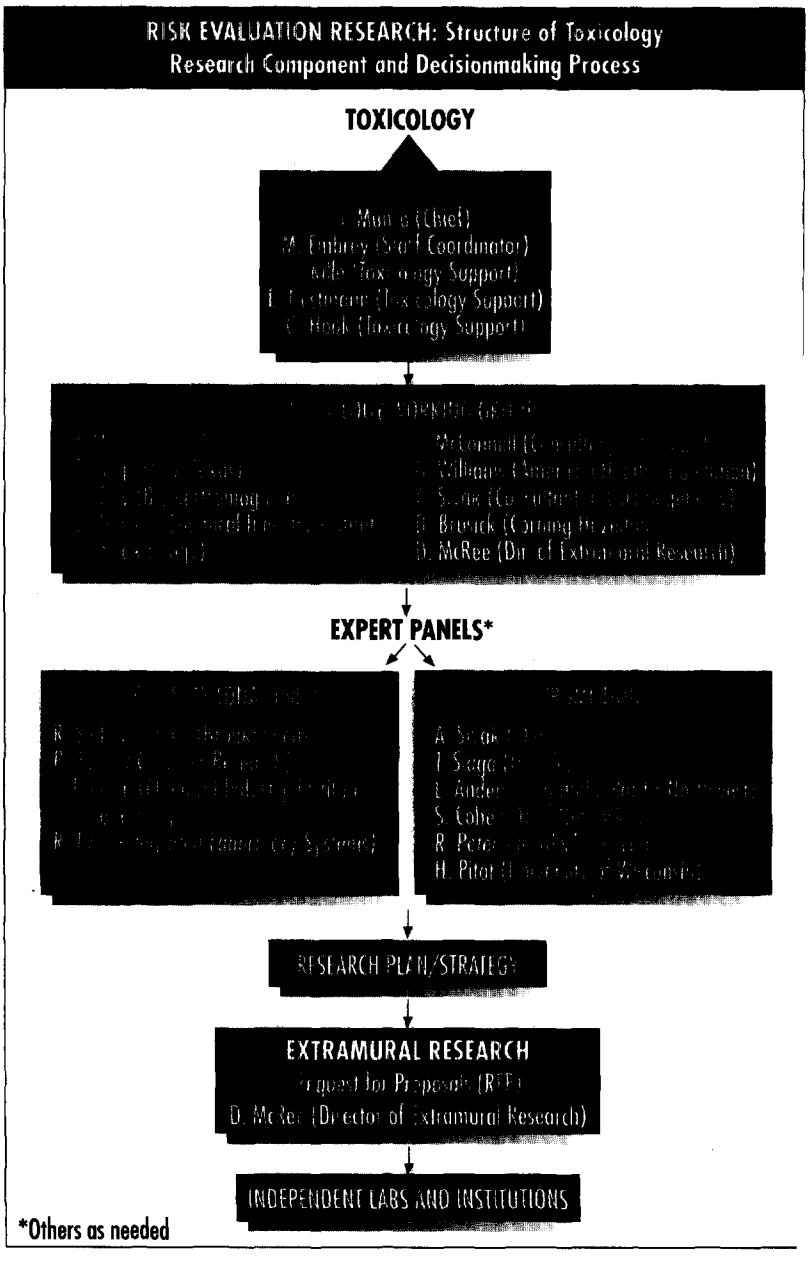
Preliminary data for FD-TD validation were developed for the Dosimetry Committee meeting held in July 1994 in Kalispell, Montana. Discussions at this meeting led to further resolution of the overall dosimetry strategy. In December 1994, experts in dosimetry, bioelectromagnetics, *in vitro* and *in vivo* toxicology, safety assessment, animal behavior, and other relevant disciplines were convened to deliberate on appropriate directions for research and development of exposure systems for *in vitro* and *in vivo* toxicology studies. Preliminary data were generated on possible source configurations for a head-only exposure system to replicate conditions of human exposure to wireless communication instruments.

Proposal Review

During Phase One, procedures for thorough and efficient review of dosimetry research proposals were developed and implemented. In addition, it was determined that, for each toxicology proposal received by the SAG, the proposed exposure system would be reviewed against the SAG's minimum criteria.

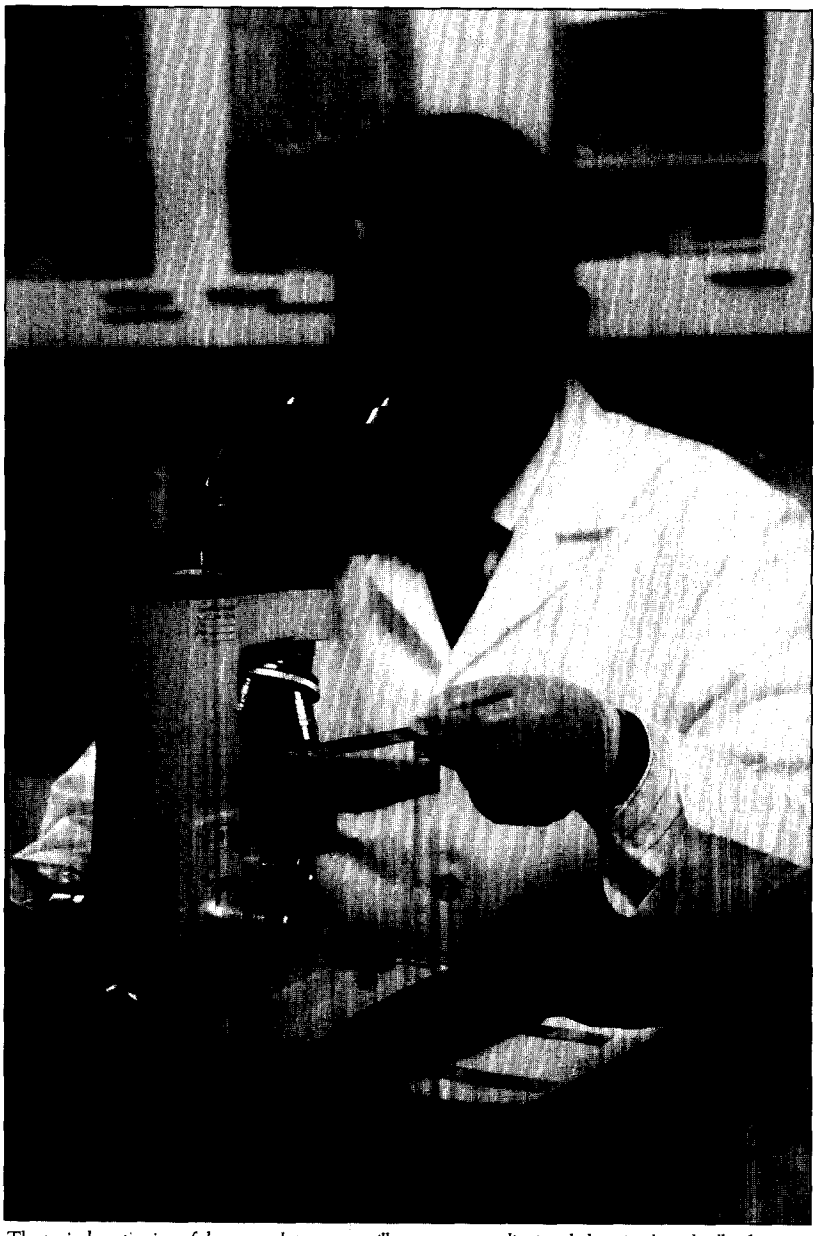
▲ DEFINITION OF TOXICOLOGY

Toxicology studies using animals and *in vitro* systems are conducted to determine the potential for a given agent or exposure to



cause adverse health effects in humans. Different types of toxicology studies can be conducted to evaluate potential toxic responses. Lifetime bioassays in rodents are recommended by the FDA as the most reliable means of determining the carcinogenic potential of exposure to a given agent. For most drugs and foods, the FDA requires lifetime bioassays in both rats and mice. Short-term studies (i.e., *in vitro* and short-term *in vivo* assays) can be used to detect potential genotoxic effects. Such studies can also provide information for evaluating possible mechanisms of action through which adverse effects can occur. When conducting genotoxicity test batteries, *in vitro* tests are generally considered to have less predictive value than tests in whole animals.

Similar requirements and guidelines exist for the U.S. Environmental Protection Agency (EPA) and various international regulatory agencies. They differ slightly in specific requirements, but all basically consider the weight of evidence from the test article's similarity to known carcinogens, the evidence from genotoxicity and other studies, and the outcome, in terms of increased tumor incidence by tissue, in the lifetime animal bioassays.



The toxicology portion of the research program will encompass studies in whole animals and cell cultures

For all guidelines, there is the intention that exposure to the test article should simulate, as closely as possible, actual conditions of human exposure. The maximal limits of the dosages are determined by experimental conditions and physiological considerations.

The research program, by following accepted approaches to determine carcinogenic potential, should provide results acceptable to regulatory review. The quality database derived from these studies will allow informed scientific decision-making based upon what we know, and permit us to dispel fear and apprehension arising from what we do not know.

Epidemiology studies require a great deal of computer power to do data linkage

HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN TOXICOLOGY RESEARCH

Literature Review

Phase One began with a completion of a comprehensive literature review that served as the basis for the SAG's *Research Agenda*. This established the framework and terms of reference around which the toxicology research program would be developed, including the methodology for reviewing toxicology research proposals.

Participation in Development of *In Vivo* and *In Vitro* Exposure Systems

Members of the Toxicology Committee assisted in the development of an exposure system by offering advice on the biological feasibility of a head-only exposure system for animal studies.

Proposals

In August 1994, the SAG published a request for proposals (RFP) in *Science* magazine, the BEMS Newsletter, and the SAG newsletter, *Cellular Telephone Update* (now *Wireless Technology Update*). Specific proposals were requested for *in vivo* and *in vitro* studies examining the possible genetic effects of typical exposures from portable cellular telephones. The RFP resulted in responses from investigators in a variety of scientific disciplines relating to genotoxicity. In addition, a number of investigator-initiated proposals (i.e., not in response to the published genotoxicity RFP) were also received. A consistent and thorough evaluative procedure was developed to carefully assess the potential relevance of any submitted proposals to the SAG research plan. Particular consideration was given to those proposals that fell under the Tier I — product safety — category.

Following the review of a number of proposals, it became apparent that there was a need to establish appropriate dosimetry guidelines and characterize both *in vivo* and *in vitro* exposure systems. The WTR will pursue relevant proposals of biological research once the exposure systems are developed.

DNA Action Plan

A DNA Action Plan was created to provide a framework for the investigation of potential radiofrequency radiation-induced genotoxicity. As part of the plan, the SAG convened an expert panel on the Single Cell Gel (SCG) assay in October 1994. In light of new data, the SAG recognized the need for specialized advice concerning the relevance of the SCG assay and the interpretation of current literature. The SCG Expert Panel prepared a position paper to advise the SAG on the assay and its strengths, limitations, and usefulness as a test for genotoxicity and its relationship to other endpoints. Also, several data sets were discussed, with particular emphasis on results from a study that used brain cells from radiofrequency radiation-exposed rats. The panel recommended that the study using microwave (2450 MHz) radiation be repeated as published by the original investigators and also repeated with correction of the deficiencies noted by the panel by either the original or alternate investigators. Questions concerning the assay and when it should be repeated were formally presented to the Peer Review Board in late 1994. The WTR has decided to repeat the study based on the board's recommendation, and is currently issuing an RFP for the work.

Tumor Promotion Expert Panel

The organization of the Tumor Promotion Expert Panel was completed during Phase One and the panel convened in the first week of 1995. Panel members are expected to assist the WTR in evaluating *in vivo* and *in vitro* promotion studies involving radiofrequency radiation, the relevance of animal promotion models to humans, and possible mechanisms of tumor promotion by radiofrequency radiation. The panel will review what is currently known from the literature regarding the study of radiofrequency radiation on tumor promotion as well as consider work in progress that has significant bearing on this question. The panel will publish a concept paper in 1995.

DNA/Genotoxicity Expert Panel

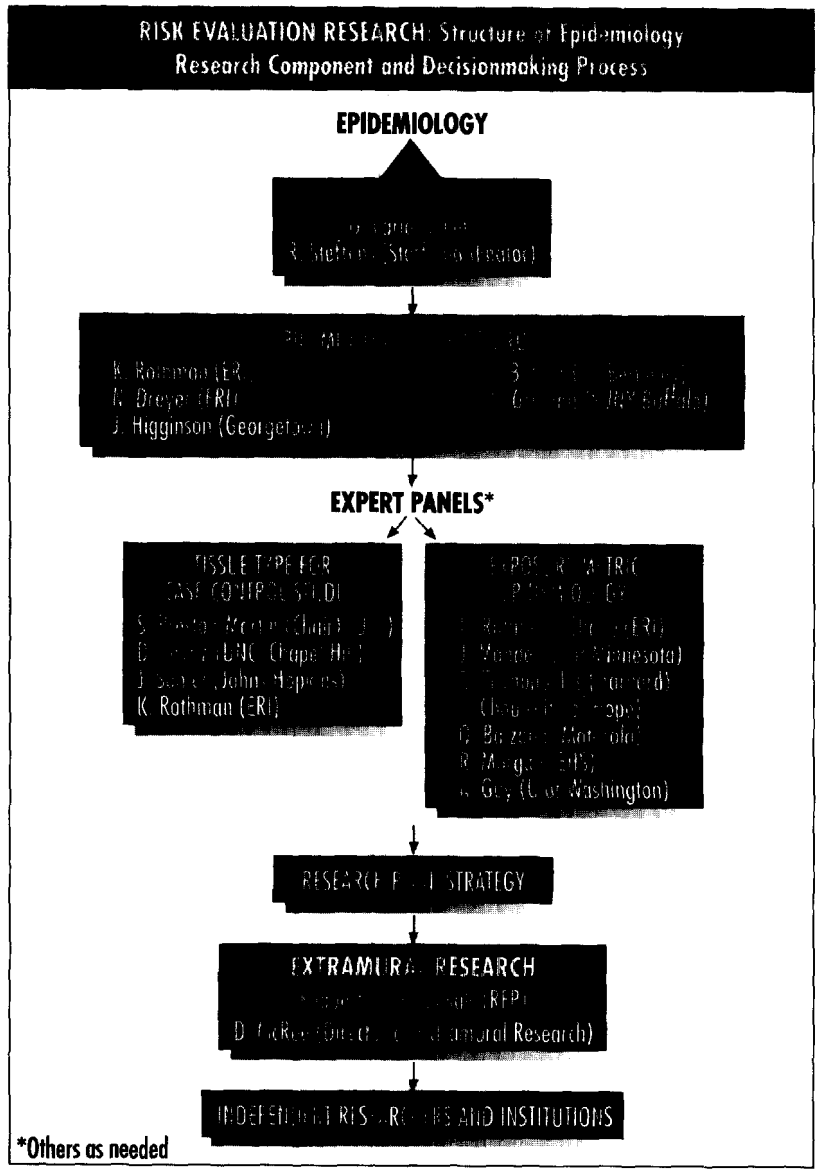
The framework for the DNA/Genotoxicity Expert Panel was established during Phase One. The panel will include experts in the fields of DNA damage and repair, molecular biology, and *in vivo* and *in vitro* genetic toxicology. Panel members will assist the WTR in evaluating and making recommendations on mechanistic as well as genotoxicity studies which have been designed to assess the potential effects of radiofrequency radiation on DNA. They will also review the available literature and provide assistance in evaluating incoming proposals.

▲ DEFINITION OF EPIDEMIOLOGY

Epidemiology research encompasses epidemiological evaluations and longitudinal surveillance of wireless technology including cellular telephone users and employing appropriate measures of real-life exposures. A series of epidemiology studies of varying but appropriate study designs has been planned to assess the possibility of cancer as a biological outcome of exposure to wireless communication instrument usage. Different study designs (cohort, case-control, cross-sectional, etc.) are necessary to fully evaluate possible causal associations. Replication of findings and consistency in the epidemiological database is served by commencing various studies simultaneously.

"The cellular telephone industry is sponsoring a research initiative through a science advisory board that includes both [epidemiological and laboratory research] that federal officials say is needed."

General Accounting Office (GAO) *Report on Safety of Cellular Telephones* November 1994



HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN EPIDEMIOLOGY RESEARCH

Pilot Studies of Cellular Telephone User Records

Dr. Ken Rothman at Epidemiology Resources, Inc. (ERI), is currently conducting pilot studies of user record utility examining the appropriate applications of cellular telephone user records, information on location of cellular system sites, and other factors. These studies will provide greater understanding of the types of information that are available and useful in order to design appropriate epidemiology studies and interpret the results. A paper describing the results of a survey conducted using a sample of this user cohort (N=5,550) to validate the correlation between user records and self-reported phone use is nearing completion and will undergo the formal peer review process for submission to the scientific literature.

Mortality Study

ERI will also compare the mortality by cause-of-death among users of portable cellular telephones with the corresponding age- and gender-specific rates among mobile telephone users. This study will follow a protocol reviewed by the Peer Review Board. These comparisons will be summarized using Standardized Mortality Ratios (SMR). ERI will also examine the SMR of categories of telephone users, using various indices of exposure. The analyses will be done separately for each phone company, as well as a combined analysis of data from all phone companies. Additional cellular telephone companies will be recruited to participate in the cohort study in order to reach an overall sample size of approximately seven million cellular phone users.

Validation Studies

Validation studies currently in progress will assess the accuracy of phone record data in determining the primary user of the cellular phone. To assure the highest quality data and scientific interpretation, all studies will be subjected to ongoing scientific peer review by the WTR and the Peer Review Board.

Concept Papers

A concept paper describing exposure assessment issues regarding cellular telephone usage is in the final development process. The paper is being written by an expert panel chaired by Dr. Ken Rothman at ERI and including Drs. George Carlo, Arthur Guy, Jack Mandel, Quirino Balzano, C. K. Chou, Robert Morgan, and Dimitrios Trichopolous. Consideration has been given to such issues as the difference from the perspective of dosimetry between ten one-minute phone calls and one ten-minute phone call. The paper also explores the appropriate ways of handling cellular telephone user records, and information on location of cellular system sites. The paper will offer a greater understanding of the kinds of information that are available and useful in order to design appropriate epidemiology studies and to interpret the results. This paper is nearing completion and will undergo the formal peer review process leading to publication.

A concept paper addressing meaningful outcomes for epidemiology studies of cellular telephone users will focus on such issues as the types of tissues likely to be affected by cellular telephone use considering current dosimetric modeling results. A panel of experts in the etiology of brain cancer and other relevant types of cancer was convened in January 1995 leading to a paper that will be incorporated into the exposure assessment paper (above). The panel is chaired by Dr. Susan Preston-Martin, and includes Drs. Rothman, Carlo, Guy, David Savitz, and Jon Samet.

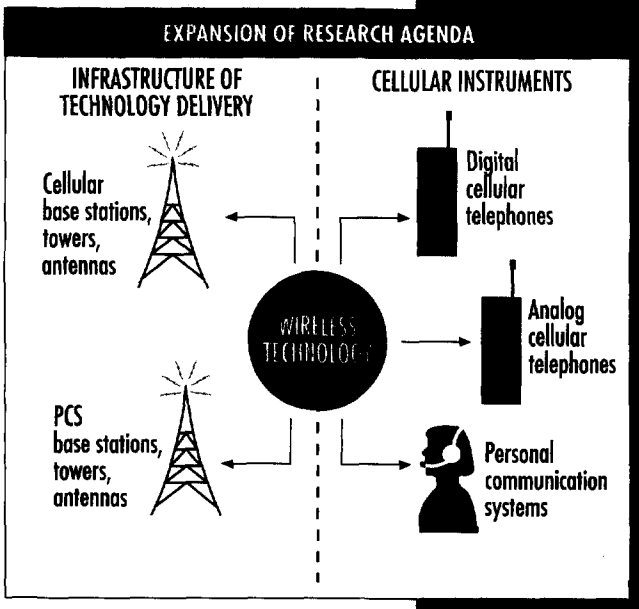
Papers will be developed by outside investigators addressing important exposure issues relevant to wireless communication instruments users to provide guidance in the epidemiology studies. The WTR will consider issues such as the importance of handedness in determining exposure, the importance of potential confounders such as wire-rimmed eye glasses, and the role of variables such as location of telephone call with respect to proximity to a base station. The unique exposure characteristics of cellular telephones must be incorporated into the evaluation of potential human effects, such as intermittent versus continuous use, and the individual characteristics of different phone models. The papers will be used to evaluate the adequacy of the assessment of human exposure to radiofrequency radiation in order to lay the foundation for the proper design and interpretation of subsequent epidemiology studies.

Exposure Weighting Scheme

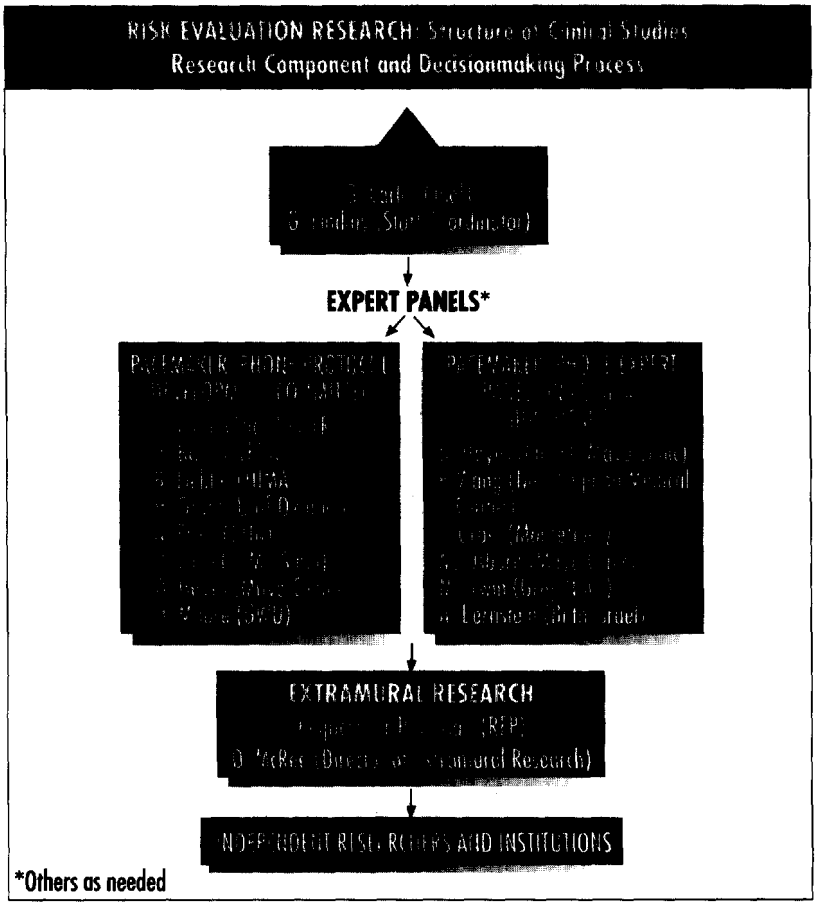
Using data provided by McCaw Cellular Communications, Inc., an exposure weighting scheme will be developed to measure the density of cell sites across the United States and proximity of cellular telephone users to a base station, as an estimate of power density. This information will be used in the epidemiology exposure metric.

▲ DEFINITION OF CLINICAL STUDIES

The clinical discipline was introduced into the Risk Evaluation Research program in 1994 when a potential public health problem involving interference from cellular phones with implanted pacemakers was identified through the Ongoing Surveillance program. Upon evaluating the issue's relevance to the *Research Agenda*, the SAG determined that a clinical study of pacemaker patients was necessary. The SAG established Clinical Studies as a distinct component of the Risk Evaluation Research program to address the interference issue, and also to have a mechanism in place to handle other clinical studies, if the need arises.



The subject matter that the SAG initially sought to study — health effects from portable cellular telephones — has now evolved into the evaluation of all wireless communication technology, including cellular base station facilities, personal communication instruments, and electromagnetic interference.



Clinical studies are planned experiments that involve human patients and are designed to observe some form of exposure. The outcomes of an exposure group are generally compared to the outcomes of a group of patients receiving a control exposure. Patients in both the groups are enrolled and followed over the same time period. In clinical studies, one uses results based on a limited sample of patients to make inferences about a general population.

HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN CLINICAL STUDIES

Protocol Development

The primary activity within the clinical studies component of the Risk Evaluation Research program was the organization and development of a protocol for the clinical study of pacemakers and cellular phones. The SAG took the lead in organizing a protocol development committee that involved a cooperative effort among the FDA; the Center for the Study of Wireless Electromagnetic Compatibility at the University of Oklahoma; physicians from the Mayo Clinic, Mt. Sinai Medical Center, and the George Washington University Medical Center; the SAG; and representatives of the pacemaker and cellular telephone industries. Dr. George Carlo served as chairman of the committee. The committee convened for several meetings and conference calls and was responsible for providing comments on each draft of the protocol. Representatives of the SAG also met with various expert working groups to discuss technical issues regarding the protocol.

Entitled A *Clinical Study to Assess the Potential for Hand-Held Wireless Telephones to Interfere with Implanted Pacemakers*, the study will be funded by the WTR and conducted at multiple institutions. All patients that present will be eligible, providing a representative sample of pacemakers, and four wireless technologies currently or soon to be available in the United States will be tested. The protocol has been finalized and results should be available by the end of 1995.

The clinical study will provide information on the interaction between cellular telephones and implanted pacemakers. To assess the public health impact of any potential interference, an expert panel of cardiologists has been formed to discuss and define the clinical significance of electromagnetic interference. The report from this group will serve as rationale for interpretation of the clinical study.

PROFILE OF RISK MANAGEMENT RESEARCH

The wireless technology research program has been designed to facilitate simultaneous work on the evaluation of potential health risks and on the development of strategies and tools to mitigate or to manage any identified health risks. The goal of the program is to bring decisionmakers to a state of readiness to manage risk as the risk evaluation research is completed.

Risk management research under the wireless technology research program is being coordinated through six distinct working groups covering the following areas:

- Wireless instrument design
- Product label modifications
- Product certification
- Usage restrictions
- Wireless technology infrastructure modifications
- Education and scientific outreach

Each of these six areas is coordinated by a working group charged with the development of intervention options and strategies specific to their area of focus. Working group members include scientists and engineers from the WTR, academia, and industry. A report entitled *Potential Public Health Risks from Wireless Technology: The Development of Data for Science-Based Risk Management Decisonmaking, Interim Status Report* was developed with input from the risk management committees.

The SAG originally forwarded the status report to the FDA to update it on the SAG's progress in the area of risk management in the summer of 1994. An updated copy was sent to the President of the Cellular Telecommunications Industry Association (CTIA) in November 1994.

RISK MANAGEMENT RESEARCH:
Working Groups Responsible for Development of Strategy for Necessary Implementation and Intervention

WORKING GROUP CHAIRS

LABELING
J. Caile
Motorola

CERTIFICATION
A. Guy
U of Washington

DESIGN CHANGE
J. Russell — AT&T
W. Pavlok — Motorola

INFRASTRUCTURE (BASE STATIONS)
A. Guy
U of Washington

PUBLIC EDUCATION
M. Volpe
Volpe Communications

USAGE RESTRICTIONS
G. Carlo
WTR/SAG Chair

Product Design Changes

The Product Design Changes Working Group developed a process to evaluate potential design change options and considered options for a peer review and evaluation process that is timely and fair, without giving undue marketplace advantage to one company over another. The group considered a number of design change possibilities, including a network-implemented call duration tone that would allow the user to know when the call reaches a certain length; a portable-implemented call duration indicator that would allow the user to access call duration information at their discretion; various vehicular antenna and regular antenna options; antenna shields, including review of existing shields currently in the marketplace; voice-operated transmission where voice activation dictates when the radiofrequency signal is sent or received; and audio headsets.

Evaluation criteria developed by the working group for these options include whether the design is available for all customers, whether the instrument will retain quality of operation, whether the instrument will maintain reliable performance in emergency situations, and whether the design change is implementable by all manufacturers. Additionally, the group developed a test evaluation for the discontinuous transmission mode.

Product Labeling

The Product Labeling Working Group assessed labeling possibilities in a number of areas, including exposure to radiofrequency energy, efficient phone operation, and electronic device compatibility. The group also evaluated a number of labeling methods and determined that a package insert would be the most appropriate way to disseminate the information.

Product Certification

The four categories of radiation standards include:

- Standards which specify safe exposure levels for humans
- Standards which limit the equipment's electromagnetic energy emissions
- Standards which are concerned with safe exposure levels for certain devices or materials (e.g., explosive devices or flammable materials)
- Interference standards limiting the impact of one emitting equipment on another electronic device

The certification effort involves the development of standardized testing techniques for evaluation of wireless instruments based on the Specific Absorption Rate (SAR). Realistic worst-case exposures will be evaluated for comparison with established exposure guidelines.

During Phase One, the efforts of the Dosimetry Committee produced an overall certification strategy and work plan. The plan includes validation of the FD-TD method for application to exposure quantification from wireless instruments and reliable measurements of human exposure for comparison to existing exposure guidelines.

Several certification programs for wireless instruments are either currently in operation or are planned. The WTR has undertaken cooperative efforts with groups conducting such programs to assure consistency and comparability of generated data.

Usage Restrictions

The Usage Restrictions Working Group is charged with evaluating emerging scientific information and making usage recommendations that will serve to mitigate any identified public health risks. Members of this group are currently involved in fundamental research under the wireless technology program, addressing dosimetry and human exposure issues.

Infrastructure Modification — Base Stations

The Infrastructure Modification Working Group is charged with evaluating the types of infrastructure changes that might be feasible to modify power, and therefore radiofrequency radiation exposure, from wireless instruments and assessing any risks associated with proposed infrastructure modifications.

The primary determinant of the amount of power employed by a handset is the distance of the user from a base station. A wireless base station plays an essential role in the wireless network by acting as both a signal relay station and a telephone switching center. If possible mitigation of a public health threat from wireless instruments entails minimizing the power being emitted from the handset, then increasing the density of base stations in a community might be a way to manage risk. Recently, citizens in communities where base stations are to be sited have raised questions regarding potential adverse impact of these base stations.

During Phase One, the working group oversaw the development of preliminary data regarding basic usage patterns and infrastructure uses. General findings include the following:

Overall usage

- Call duration seems to be independent of system, geography, or demographics
- Around 80% of all calls are less than two minutes in duration, in both rural and urban areas

Patterns of users

- The majority of usage is in the lower-powered urban and suburban areas
- As the average usage increases, users tend to be located in the lower-powered environments

Overall system power trends

- As the systems grow, they tend to power down
- Powering down reduces the likelihood of portables operating at full power

Portable power trends

- The amount of time that a portable phone will operate at full power in an urban area could be as low as 5%; rural areas could have a minimum time of 50%

The working group sponsored a National Symposium on Wireless Transmission Base Station Facilities on October 28, 1994. Symposium participants included scientists, engineers, land-use experts, public policy officials, and economists from the Federal Government, academia, industry, and the non-profit community.

The symposium, coordinated by Federal Focus, provided an environment in which scientific information on base stations was shared and consolidated. Agenda sessions included a description of current and planned technologies, base station facilities and electromagnetic interference and compatibility, typical exposures to base station radiofrequency and exposure standards, and land use issues surrounding the siting of base stations.

A monograph is being prepared which compiles the information presented at the symposium and provides a primer on wireless technology and base station facilities.

Education and Scientific Outreach

This working group has been instrumental in the development and dissemination of information regarding the wireless technology research process, including both the risk evaluation and the risk management components. Some of the group's Phase One activities included: publication of the *Cellular Telephone Update* newsletter (now *Wireless Technology Update*), which has a circulation nearing one thousand; coordination of briefings regarding the wireless technology research program for the GAO, FDA, EPA, FCC, NTIA, OTA, HHS, Department of Commerce, U.S. Congress, and the White House; and coordination of informed responses to public, media, and scientific inquiries regarding wireless technology and the research program.

"The purpose of the symposium is to have experts share their insight and experience on the changing role of wireless transmission base station technology and provide a forum for coordinating interagency scientific discussions."

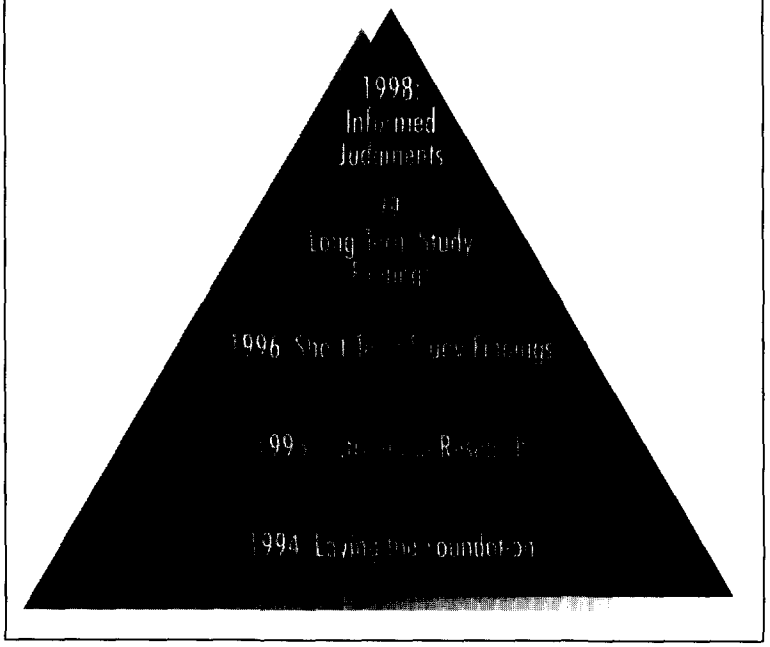
Dr. George L. Carlo
Base Station Symposium
October 1994

"The Scientific Advisory Group's program is one of the largest independent research efforts in the world. We are moving forward with the input of more than 150 scientists in the United States and abroad. In science, it is most important to be right, not hasty."

Dr. George L. Carlo
Chairman

December 1994

GETTING TO THE ANSWERS



Report Recommendations

In November 1994, at the time the SAG forwarded the risk management status report to CTIA, the SAG made three specific recommendations to industry. These recommendations were not based on public health urgency, but as appropriate and effective steps to enhance and sharpen the industry's ability to be responsive should the need for risk management intervention arise. The recommendations were to:

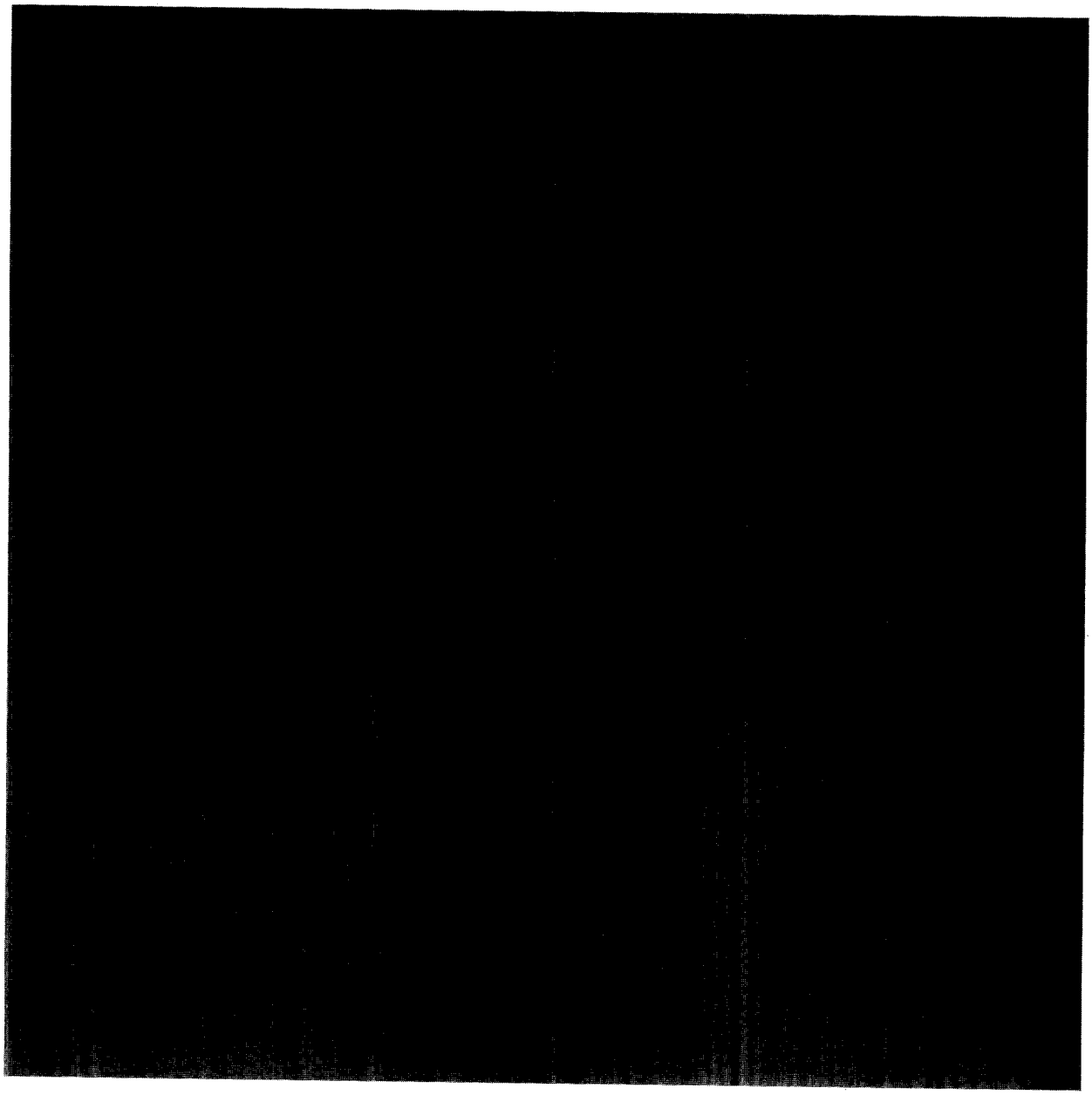
- Adopt standardized labeling of wireless instruments
- Develop standardized information for dissemination to member companies and to the public
- Adopt an industry-wide instrument certification program that requires certified phones to meet all appropriate standards

The SAG Product Labeling Working Group, in cooperation with the CTIA, developed guidelines for usage information to insert in new phone packaging. The SAG endorsed these efforts; however, as these guidelines do not address health concerns, the SAG recommended that CTIA explore the possibility of incorporating the FDA's talk paper, "Update on Cellular Phones" in the package insert to complement the usage guidelines.

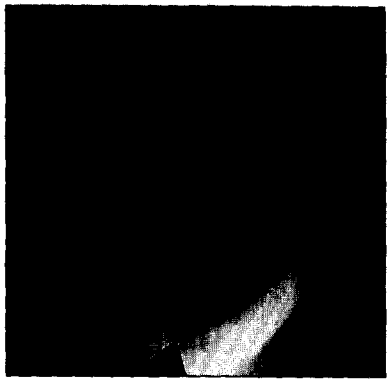
The SAG also suggested that CTIA prepare and forward standardized material describing the scientific program and its progress to its members. They recommended that the material be checked for accuracy by the SAG and organized to facilitate periodic updates. This material should form the basis for all information disseminated to the public.

Finally, the SAG recommended that the industry develop an independent structure through which those cellular telephone manufacturers who do not already do so have their products tested to ensure they meet current safety standards. The Product Certification Working Group is developing standardized guidelines to be used for certification.

APPENDICES



MEMBER BIOGRAPHIES



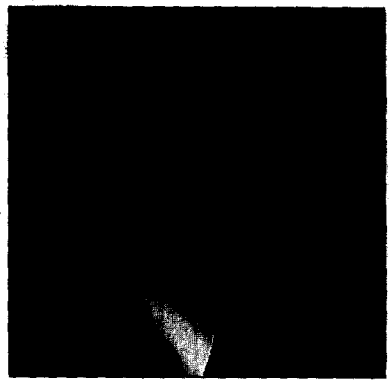
Dr. George L. Carlo is an epidemiologist and the chairman of Health & Environmental Sciences Group, Ltd., which specializes in assessing and managing risks to health, including risks from the environment, pharmaceuticals, and consumer products. He also studies the safety and efficacy of drugs and medical devices.

Dr. Carlo serves on the adjunct faculty of the George Washington University School of Medicine and Health Sciences. He previously served on the faculties of the University of Arkansas for Medical Sciences, the State University of New York at Buffalo School of Medicine, and the Roswell Park Memorial Institute.

Dr. Carlo served on the U.S. Congress Office of Technology Assessment Agent Orange Advisory Panel, currently chairs the Wireless Technology Research, L.L.C., is a member of the National Institute for Allergy and Infectious Diseases' Low-Dose Oral Alpha-Interferon Clinical Trial Planning Committee, and is a scientific advisor to various private concerns. He is a Fellow of the American College of Epidemiology.

Dr. Carlo earned his B.A., M.S., and Ph.D. from the State University of New York at Buffalo. He earned his Juris Doctor from the George Washington University. He is a member of the Society for Clinical Trials, the Society for Epidemiologic Research, the American Public Health Association, and numerous other professional public health, science, risk analysis, and occupational and environmental health associations and organizations.

Dr. Carlo has published extensively, including research articles, commentaries, book chapters, and health policy papers addressing environmental, occupational, and public health issues and health sciences. He has been invited to testify before Congress, government, and regulatory agencies. Dr. Carlo has been listed in *Who's Who in Science and Engineering*, *Who's Who in Medicine and Healthcare*, and *Who's Who in the World*.



Dr. Arthur W. Guy is one of the world's leading experts on bioelectromagnetic research. A former President of the Bioelectromagnetics Society (1983-84), he has received numerous awards in the fields of bioelectromagnetics and microwave power. In 1993, he became a member of the SAG and, subsequently, the WTR.

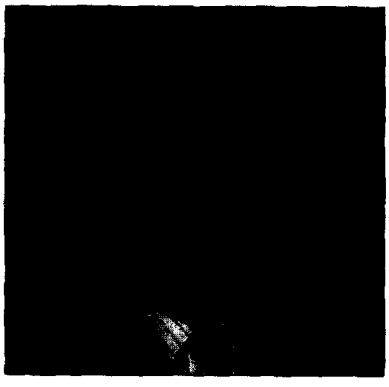
During his early career, Dr. Guy served as Electronics Technician in the U.S. Air Force, Research Engineer in the Antenna Research Group, Boeing Aerospace Company, and Researcher on VLF antennas buried in polar ice caps for the Department of Electrical Engineering, University of Washington. He acted as Consultant to the Department of Rehabilitation Medicine, studying effects of electromagnetic fields (EMF) on living tissue, and joined the faculty in 1966.

At the University, Dr. Guy was Professor in the Center for Bioengineering, had a joint appointment as Professor in Rehabilitation Medicine and Adjunct Professor in Electrical Engineering, served as

Director of the Bioelectromagnetics Research Laboratory, and is presently Professor Emeritus in the Center for Bioengineering and Rehabilitation Medicine.

Dr. Guy is Vice Chairman of the Institute of Electrical and Electronics Engineers (IEEE) Standards Coordinating Committee SCC-28 on Nonionizing Radiation and a member of SCC-28 Subcommittee IV, which developed protection guidelines for human exposures to radiofrequency fields in 1974 and 1982. He is a member of the National Council on Radiation Protection and Measurement's Scientific Committee 89 on Nonionizing EMF and previously chaired its Scientific Committee 53, responsible for biological effects and exposure criteria for radiofrequency fields. He chaired the IEEE Committee on Man and Radiation (COMAR), is a member of the U.S. National Committee of the International Union of Radio Science (URSI) Commissions A and K, and has served on the U.S. Environmental Protection Agency Scientific Advisory Board Ad Hoc Committee on Biological Effects on Radiofrequency Fields. Dr. Guy was a participant in the US-USSR Environmental Health Cooperative Program from 1974 to 1983, and served on the editorial boards of several bioelectromagnetic journals prior to his retirement.

He received his B.S., M.S., and Ph.D. in Electrical Engineering from the University of Washington, Seattle. He holds memberships in Phi Beta Kappa, Tau Beta Pi, Sigma Xi, the American Association for the Advancement of Science and the American Polar Society, and is a Fellow of the IEEE and the International Microwave Power Institute.



Dr. Ian C. Munro is a leading authority on toxicology and has over 25 years experience in dealing with complex regulatory issues related to product safety. He has in excess of 150 scientific publications in the fields of toxicology and risk assessment. In 1993, he became a member of the SAG and, subsequently, the WTR.

Dr. Munro formerly held senior positions at Health and Welfare Canada as Director of the Bureau of Chemical Safety and Director General of the Food Directorate, Health Protection Branch. While with the Health Protection Branch, Dr. Munro was responsible for research and standard setting activities of the Branch related to microbial and chemical hazards in food and nutritional quality of the Canadian food supply.

He also has contributed significantly to the development of risk assessment procedures in the field of public health both nationally and internationally through membership in various committees dealing with the regulatory aspects of risk assessment and risk management of public health hazards. A member of the Board of Directors of the Toxicology Forum, Dr. Munro also holds memberships in the Society of Toxicology and the American College of Toxicology.

He has served on numerous national and international committees, including those of the World Health Organization, the International Agency for Research on Cancer, and the National Academy of Sciences. Dr. Munro is a fellow of the Royal College of Pathologists, London. He also was formerly Director of the Canadian Centre of Toxicology at Guelph, Ontario, and serves as adjunct professor in the Department of Nutritional Sciences at the University of Guelph.

Dr. Munro is a graduate of McGill University in Biochemistry and Nutrition. He also holds a Ph.D. from Queen's University in Pharmacology and Toxicology.

10 April 1995

Keith O. Fultz
Assistant Comptroller General
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
441 G Street, N.W.
Washington, DC 20548

RE: **Telecommunications: Status of Research on the Safety of Cellular Telephones, November 1994**

Dear Mr. Fultz:

After careful review of your evaluation of the status of research on cellular telephones, we are pleased to report that The Scientific Advisory Group on Wireless Technology (SAG) has adopted your recommendations regarding the independence and objectivity of our research program and the role of the federal government in the program.

As you are aware, our program was established in early 1993. The surveillance and research effort was launched pursuant to the wireless telecommunication industry's public commitment to support the funding of independent, rigorous scientific research into the public health impact of wireless technology. The independent scientific program we subsequently developed was framed in accordance with the following criteria:

1. The program must be independent of industry influence so that the results would be acceptable to public health decisionmakers in the scientific community, government, industry, and the community;

2. The program must adhere to the highest of scientific standards to guarantee scientific rigor;

3. The program must encompass a rapid trigger for public health intervention, if any adverse impact of wireless technology is discovered;

4. The program must encompass ongoing coordination with government decisionmaking bodies and the scientific community;

5. The program must involve significant funding to gain answers to critical public health questions in a defined time frame.

1711 N Street, NW Suite 200, Washington, DC 20036
(202) 833-2800 *telephone* ◆ (202) 833-2801 *facsimile*

From the outset, the scientific rigor of our program has been built upon the expertise of the scientists and research institutions involved in this effort. In developing our research agenda, we reviewed all of the potentially relevant data available and drew upon the ideas of more than 150 of the most informed scientists around the world. We then subjected our research agenda to an exacting scientific peer review process by a Peer Review Board of esteemed public health professionals, coordinated through the Harvard University School of Public Health. As we proceed to the "extramural" stage of our work, in which we contract with expert scientific investigators at universities, laboratories and other facilities, we will continue to maintain ongoing interactions with scientists in government and private institutions, both in the United States and abroad. We will also require our contractors to submit their work for publication in the open scientific literature. We are confident that our program will provide comprehensive and essential information regarding any health risks from wireless technology.

From the beginning, we too have believed that the independence of our research effort was paramount to the usefulness of our work. To this end, we have relied upon the integrity of the scientists working in our program, the integrity of the prestigious institutions they represent, the integrity of the scientific peer review program, the openness of our processes, the involvement of the federal government, and the promise of industry to provide financial support without any effort to interfere with or influence the scientific work.

In your report, you implied that the promise of non-interference by industry was not sufficient to satisfy everyone that industry would not influence the scientific process. To address this issue constructively, we have adopted the GAO's recommendation of an independent, formal funding mechanism covering the entire research program.

As of March 31, 1995, a new administrative structure, Wireless Technology Research, L.L.C. (the WTR), will carry forward the implementation of the program as it enters its extramural stage. The WTR is an independent, non-profit organization that will be directed by the same persons who have been members of the SAG.

Adopting the GAO's recommendations, in the context of the extramural stage of the research program, necessitated expansion of the SAG's duties and responsibilities. The original structure of the SAG focused on developing the scientific underpinnings of the research program. The SAG entered into relatively small contracts and grants to provide for initial research. The extramural stage will involve large contracts and thus will require enhanced financial management capability. The WTR will furnish that capability, in addition to the scientific program management and analysis that the SAG provides. The WTR now has exclusive contracting authority, using unrestricted deposit-only funds in an escrow account financed by industry. It has also hired administrative staff to manage, audit and report on the flow of funds through the research program. The WTR's principles governing the management of the escrow account provide for full and public disclosure of the financial structure and will ensure the integrity of the program and the resulting research.

Finally, in keeping with your recommendation to enhance coordination with government agencies, I am pleased to report that, on March 17, 1995, we held the first in what will become regular working sessions with government agency scientists. This very productive day-long session was facilitated by Dr. Elizabeth Jacobson of the FDA, and included scientists from the FDA, EPA, FCC, NTIA, NCI and NIOSH.

We believe that incorporating the recommendations of the GAO has enhanced our program and we thank you for your thoughtful input.

Sincerely,

George L. Carlo, Ph.D., M.S., J.D.
Chairman

cc: The Honorable William J. Clinton
The Honorable Jack Fields
The Honorable Edward J. Markey
The Honorable Carlos J. Moorhead
The Honorable Thomas Bliley, Jr.
The Honorable John D. Dingell
The Honorable Henry A. Waxman
Chairman Reed Hundt
Commissioner James H. Quello
Commissioner Andrew Barrett
Commissioner Rachelle Chong
Commissioner Susan Ness
The Honorable David Kessler
The Honorable Phil Lee
The Honorable Carol M. Browner
Dr. Elizabeth Jacobson

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American Public Health Association
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AT&T Bell Laboratories
AUSA Research
Bailey Research Associates
Battelle Pacific Northwest Laboratories
Ben-Gurion University of the Negev
The Bioelectromagnetics Society
British Columbia Cancer Research Centre
California Institute of Technology
Carnegie-Mellon University
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Chemical Industry Institute of Toxicology
City of Hope National Medical Center
Clemson University
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Commsphere
COST 244
CSIRO Australia
Danish Cancer Society
Danish Institute for Clinical Epidemiology
ENSEEIHT
Environmental Health Strategies, Inc.
Epidemiology Resources, Inc.
Electromagnetic Energy Association
European BioElectromagnetics Association
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Finnish Institute of Occupational Health
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GenPharm International
Georgetown University
The George Washington University
Georgia Institute of Technology
Georgian Academy of Sciences
Harvard University School of Public Health
Howard University
IIT Research Institute
Inhalation Toxicology Research Institute
The Institute for Regulatory Policy
Institute of Experimental Radiology
Institute of Occupational Health
Integrated Laboratory Systems
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International Life Sciences Institute
International Union of Radio Science
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Jewish General Hospital
John B. Pierce Laboratory
The Johns Hopkins University
Lenox Hill Hospital
Loma Linda University
Lund University Hospital
The Mayo Clinic
Medical College of Virginia
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Memorial Sloan-Kettering Cancer Center
Michigan State University
Mt. Sinai Hospital
New York Medical College
Northwestern University
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Sintef Unimed
Somerville College
Southwest Research Institute
State University of New York at Buffalo
State University of New York at Geneseo
Statistics Sweden (SCB)
The Swedish Council on Technology Assessment in Health Care (SBU)
Swiss Federal Institute of Technology
Technical University of Wroclaw
Telia Research AB
Thames Cancer Registry
TNO Defense Research
The Toxicology Forum
Trinity University
Underwriters Laboratories, Inc.
University of Alabama at Birmingham
University of Alberta
University of Bradford
University of California at Berkeley
University of California at Davis
University of California at San Francisco
University of Colorado at Boulder
University of Frankfurt
The University of Illinois at Chicago
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University of Kuopio
University of Maryland
University of Michigan
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The University of Texas Health Science Center at San Antonio
University of Turin
University of Utah
University of Victoria
University of Washington
University of Wisconsin Medical School
University of Zurich
Virginia Commonwealth University
VITO
Washington University
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Government Agencies, Departments, and Research Facilities
Armstrong National Laboratory
Brookhaven National Laboratory
Brooks Air Force Base
Department of Commerce
Department of Energy
Department of Health and Human Services
Department of the Air Force
Department of the Navy
Federal Communications Commission
Food and Drug Administration
National Cancer Institute
National Council on Radiation Protection and Measurement
National Institute of Applied Sciences
National Institute of Environmental Health Sciences
National Institute of Occupational Safety and Health
National Institute of Public Health
National Institutes of Health
National Radiological Protection Board
National Research Institute for Radiobiology and Radiohygiene
National Telecommunications Information Administration
Naval Aerospace Medical Research Laboratory
Occupational Safety and Health Administration
U.S. Congress Office of Technology Assessment
U.S. Environmental Protection Agency
U.S. General Accounting Office
U.S. House of Representatives
U.S. VA Medical Center
Veterans Administration Medical Center
Walter Reed Army Institute of Research
White House Office of Science and Technology Policy

Industry Support

AGT Mobility Inc.
ALLTEL Mobile Communications, Inc.
AMC Cellular Associates
AT&T
Activated Communications, Inc.
Advantage Cellular Systems, Inc.
AirTouch Cellular
Alpha Cellular dba Cellular One
American PCS, L.P.
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Bristol Bay Cellular Partnership
C.C. Cellular
Cal-North Cellular
Carolina West Cellular
Cellular Communications, Inc.
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Cellular One of Amarillo
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Larsen Cellular Communications, Inc.
Leaco Rural Telephone Cooperative, Inc.
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MINNESOTA RSA 9 LTD. PART.
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Northern Telecom Inc.
OKI Telecom
Oklahoma Western Telephone Co.
OneComm Corporation
Oneonta Telephone Co., Inc. dba OTELCO
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Valley Telecom
Vanguard Cellular Systems, Inc.
Vitel Cellular
WESTERN MAINE CELLULAR, INC.
West Central Cellular
Western Wireless Corporation
Wireless One Network
WirelessCo

Many other unnamed individuals and institutions contributed to Phase One of our research program and to these we also extend our sincere thanks.

The WTR

Wireless Technology Research, L.L.C.
1711 N Street, NW
Suite 200
Washington, DC 20036

Phone 202-833-2800
Fax 202-833-2801
e-mail 73763.424@compuserve.com